REMARKS

Reconsideration and allowance of the captioned patent application is respectfully requested.

Please note a Request for a Corrected Filing Receipt and Filing Date was submitted on December 9, 2005. It does not appear in th PAIR system, and is therefore being resubmitted herewith.

The captioned patent application relates to a method of treating obesity using compounds that antagonize CB1 receptors and inhibit the enzyme 11β-HSD1, without substantially altering cellular ion channel activity. The compounds useful herein are further selective for CB1 receptors relative to CB2, thereby reducing side effects that are associated with CB2 antagonism.

Claims 1, 4-14, 25 and 28 have been amended. Claims 15-24 have been cancelled without prejudice. Claims in the case are now 1-14 and 25-28.

The Examiner has rejected the application under 35 USC 112 paragraph 1 for lack of adequate written description. The Examiner has characterized the method in that low activity across ion channels is sought. This bears clarification. Low levels (or high molar IC_{50} values) are desired and achieved to minimize side effects. High activity would correlate with low molar IC_{50} concentration. A drug with an IC_{50} of greater than 2μM in the ion channel assay would thus have low activity and would thus be desirable. Applicants have provided numerous examples of CB1 receptor antagonists as well as selective 11β-HSD1 inhibiting compounds. The characterization of these compounds in their activity across ion channels is routine, taking into account the assays referred to in the specification. Test data has been provided on pages 33-34. No further data is necessary in this regard.

The Examiner relied upon U. California v. Eli Lilly (U. Cal.) in rejecting the present application. This case is not controlling in determining whether the present application has met the written description requirement. U. Cal. is primarily a sovereign immunity and forum litigation, holding that sovereign immunity was not relevant because the State of California was not a defendant directly or indirectly through the University of California, and that the federal courts may transfer any civil action for the convenience of the parties.

The U. Cal. patent held invalid because it failed to describe the invention with all of the claimed limitations. Here, Applicants have described the invention, namely a method of treating obesity, along with a routine test that can be used to confirm ion channel activity. No further description is necessary. Thus, U. Cal. should be inapplicable here.

The claims were also rejected for non-enablement, alleging undue experimention would be required. Applicants respectfully disagree. There are numerous patents and published applications that disclose compounds that are useful as 11β-HSD1 inhibitors. Similarly there are numerous patents and published applications that disclose CB1 receptor antagonists. It is routine to confirm that these disclosed compounds have or do not have ion channel acitivity, according to the procedures set forth in the present application. Two simple screening tests are required to confirm that a compound has or does not have utility in the claimed method, if compounds of the patents and published applications are used as a starting point. For compounds that are disclosed as effective inhibitors of 11β-HSD1, one of ordinary skill would screen for CB1 receptor antagonist activity, followed by a screen to confirm a lack of ion channel activity. Likewise, for CB1 receptor antagonist compounds, the screen would seek out compounds that selectively inhibit 11β-HSD1, and then another screen to confirm a lack of ion channel activity. It is difficult to envision a two-step screening process as constituting "undue" experimentation, since the screens are quick and simple, and since there are numerous compounds disclosed as having either 11β-HSD1 inhibiting or CB1 receptor antagonist acitivity thus forming a narrow starting point from which further refinement is achieved. Hence, the number of compounds or examples disclosed in the application should not be dispositive as to patentability of the claimed invention.

In summary, it is urged that the claimed invention is patentable. Accordingly, reconsideration and allowance of the captioned patent application are respectfully requested. If there are any questions in connection with this application, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

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